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5 510(K) SUMMARY

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. § 807.92.

Submitter:

Medic4All (Israel) LTD.

NOV - 8 2006

10 Hamefalsim Street, POB 4222
Petach Tikva, Israel 49000
Phone number: +972-3-9226610
Fax number: +972-3-9226615

Contact Person:

Jonathan S. Kahan
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Phone: (202) 637-5794

Date Prepared: July 21, 2006

Name of the Device:

Medic4All Telemedicine System VMS-01

Predicate Devices:

The VMS-01 is substantially equivalent to:

- The Philips Medical Systems M3810A TeleMonitoring System with M3812B TeleStation (K023749).
- The BL-Healthcare, Inc. Remote Care Management System (K051470).

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Intended Use / Indications for Use

The Medic4All Telemedicine System Model VMS-01 is intended to collect and transmit physiological information, such as non-invasive blood pressure, via standard telephone lines or the internet to local or remote computer systems for use by the patient or a healthcare professional.

Technological Characteristics

Medic4All's VMS-01 telemedicine system (VMS-01) is a wireless telephonic/internet-based physiologic monitoring system, designed for care of patients requiring periodic monitoring. It is designed for interactive, remote, physiological data measurement, transmission, processing, storage and display of data. Additionally, the system allows optional verbal and video conferencing between a care giver and a patient through common telephone lines or the internet and optional hardware.

Performance Data

Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the telemedicine system. Testing involved EMC/Electrical safety; unit testing; integration testing; data integrity testing; usability testing; environmental testing; compatibility testing; performance testing, system testing, and load/performance testing for the whole telemedicine system. In all instances, the VMS-01 functioned as intended.

Substantial Equivalence

The VMS-01 system is substantially equivalent to the Philips Medical Systems M3810A TeleMonitoring System with M3812B TeleStation (K023749) and the BL-Healthcare, Inc. Remote Care Management System (K051470). The VMS-01 has the same intended uses and substantially similar indications, technological characteristics, and principles of operation as these predicate devices. The minor differences in indications for use and technology between the VMS-01 and the predicate devices raise no new issues of safety or effectiveness, as demonstrated by performance test data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2006

Medic4All Ltd.
c/o Mr. Jonathan S. Kahan
Partner
Hogan & Hartson
555 Thirteenth St. NW
Washington D.C. 20004

Re: K062127
Trade Name: Wireless Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: October 24, 2006
Received: October 24, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K062127

Device Name: **Telemedicine System Model VMS-01**

Indications for Use:

The Medic4All Telemedicine System Model VMS-01 is intended to collect and transmit physiological information, such as noninvasive blood pressure, via standard telephone lines or the internet to local or remote computer systems for use by the patient or a healthcare professional.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062127